IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/796,239 | Examiner: David M. Shay

Filing Date: March 9, 2004 | Group Art Unit: 2156

Inventor: Fred T. Lee, Jr. | Confirmation No.: 3769

Title: *Multipolar Electrode System for Volumetric Radiofrequency Ablation*

Attorney Docket No. 1512.166

APPELLANTS' APPEAL BRIEF

Mail Stop – Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On or about April 2, 2010, Appellant received a Final Rejection of claims 1-9, 13, 16-22, and 28-32 pending in this application. A Notice of Appeal was filed on July 1, 2010 together with a Request for a Pre-Appeal Brief Review. A Notice of Panel Decision transferring this case to the Board of Patent Appeals and Interferences was received September 24, 2010.

The following Appellant's Appeal Brief is being submitted pursuant to 37 CFR §41.37. Please charge any additional fees to Deposit Account No. 50-1170.

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REAL PARTY IN INTEREST

The real party in interest of the above-identified application is Wisconsin Alumni Research Foundation, a Wisconsin Corporation, located and doing business at 614 Walnut St., 13th Floor, Madison, WI 53726.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

The Examiner has rejected claims 30-32 under 35 USC §112, first paragraph as failing to comply with the written description requirement. The Examiner has rejected claims 1-9, 13, 16-22, and 28-32 under 35 USC §103(a) as being unpatentable over Gough (US Patent 5,728,143) in combination with Swanson (US Patent 6,488,679).

All of the claims have been finally rejected, and the rejection of claims 1-9, 13, 16-22, and 28-32 is appealed herein. The claims, as they presently stand, are found in the Claims Appendix to this Appellant's Appeal Brief.

STATUS OF AMENDMENTS

An Amendment was filed by Applicant on or about December 18, 2009 in response to an Office Action in a second Request For Continuing Examination made September 16, 2009. On March 29, 2010, the Examiner issued a third Final Office Action rejecting all claims. No claim amendments are now pending.

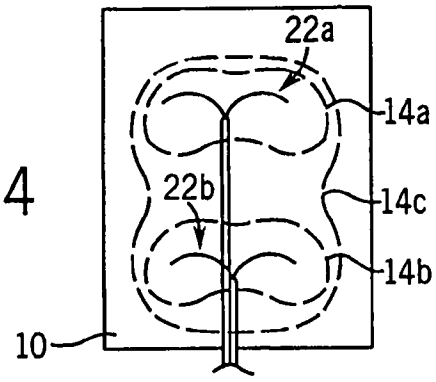
SUMMARY OF CLAIMED SUBJECT MATTER

(*paragraph numbers are provided according to the published application 2004/0230187*)

The present invention relates to medical devices used for treatment of cancer. In particular, the invention provides an electrode system for radiofrequency ablation of cancer tumors. *Specification, paragraph [0003].*

More specifically, the invention uses axially displaced umbrella electrodes supported by outwardly nonconductive shafts. Such umbrella electrodes provide wires that extend radially from an electrode shaft like the ribs of an umbrella. A power supply is connected between the axially spaced wires of the umbrella electrodes to induce a current flow between these two separated wire sets to permit simultaneous treatment of a volume between planes defined by the axially spaced, radially extending umbrella electrodes. *Specification, paragraphs [0009]-[0010]; Figures 1, 3, 4.*

FIG. 4



By employing axially separated multiple umbrella electrode prongs 22a and 22b, the latter which define opposed planes, and operating them to provide current flow between the planes, a substantially larger and more uniform lesion 14c can be created. *Specification, paragraph [0032].* The invention provides an improvement over both prior art "monopolar" and

"bipolar" treatment methods by permitting a uniform treatment volume while decreasing treatment time and simplifying control of the treatment. *Specification, paragraph [0009].*

The above description gives an overall summary of a preferred embodiment of the invention. The following summarizes the claims 1, 8, 28, and 29 at issue. The remaining claims are considered to stand or fall with one of the below summarized claims.

Claim 1 is an independent method claim that recites a method for ablating a volume of tissue in a patient by inserting a first and second support shaft (18a, 18b or 42 and 18c), the latter with an electrically insulated outer surface (46), through the patient's skin. *Specification, paragraphs [0040], [0015].* At least three electrode tips (22a) are extended from the first support shaft at an axial first position on one side of a center of the volume of tissue to be ablated (14). *Specification, paragraph [0015].* At least three electrode tips (22b) are extended from the second support shaft at a second axial position having a predetermined spacing from the first axial position. *Specification, paragraph [0032], [0012].* Power (28) is applied between the two sets of electrode tips (22a and 22b) causing current flow between them. *Specification, paragraph [0031].* A portion of the second support shaft that extends from the first axial position to the second axial position is insulated (46) so as not to divert current from the volume of tissue being ablated. *Specification, paragraphs [0029], [0040].*

Claim 8 is a method claim dependent on claim 1 wherein the electrode tips are aligned between the sets at the two axial positions. *Specification, paragraph [0012].*

Claim 28 is an apparatus claim dependant on claim 16 (having analogous limitations to claim 1 above) in which the two support shafts are co-axial. *Specification, paragraph [0040].*

Claim 29 is an apparatus claim dependant on claim 16 in which the two support shafts are side-by-side. *Specification, paragraph [0042].*

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review are as follows:

Whether the drawings are objectionable as failing to show every feature of the invention specified in the claims.

Whether claims 30-32 fail to comply with the written description requirement under 35 USC §112, first paragraph.

Whether claims 1-9, 13, 16-22, and 28-32 are unpatentable over Gough in combination with Swanson under 35 USC §103(a).

For the purposes of this appeal, claims 1-7, 9, 13, 16-27 and 30 stand or fall together, independently from the other claims appealed herein; claim 8 stands or falls, independent from the other claims appealed herein; claims 28 and 31 stand or fall together, independently from the other claims appealed herein; and claims 29 and 32 stand and fall independently from each other and the other claims appealed herein.

ARGUMENT

I. Drawing Objections

The Examiner has objected to the drawings as failing to show:

> the first and second electrode set each comprising three wires positionable at angularly offset radial points around the shaft configuration.

These wire sets are shown in Figs. 1, 2, 3, 4, 5, and 7 where the shaft configuration is provided by shafts 18a and 18b (shown in Figs. 3 and 4) and the three wires are trifurcated electrodes 22a and 22b (shown in Figs. 1, 2, 3, 4, 5, and 7). Thus, these claim elements are clearly shown in the drawings.

II. New Matter Rejection of Claims 30-32.

The Examiner has also objected to the claim phrase:

> the first and second electrode set each comprising three wires positionable at angularly offset radial points around the shaft configuration,

under 35 USC §112 as introducing new matter. It should be noted that since the claims (which also form part of the specification) have been both rejected and objected to, this issue is properly appealable. *See MPEP 2163.06 II.*

As discussed above, these wire sets are shown in Figs. 1, 2, 3, 4, 5 and 7 and described in the accompanying text of the specification. For example, the shaft configuration is provided by shafts 18a and 18b as shown in Figs. 3 and 4, and described in the accompanying text at paragraph [0042]. The three wires are trifurcated electrodes 22a and 22b as shown in Figs. 1, 2, 3, 4, 5, and 7 and described in the accompanying text, for example, at paragraph [0028]. Accordingly, no new matter has been added.

III. Rejection of Claims 1-9, 13, 16-22 and 28-32 under 35 USC §103(a)

The Examiner has rejected claims 1-9, 13, 16-22, and 28-32 under 35 USC §103(a) as being unpatentable over Gough ('143) in combination with Swanson. The application of 35 USC §103 to the identified claims begins at page 22 of the Final Office Action of April 2, 2010 (henceforth "Final Office Action").

A. Axially spaced sets of three radially extending electrode tips

As generally agreed by Applicant and the Examiner, neither Gough nor Swanson teach axially spaced sets of three radially extending electrode tips. *See Final Office Action, page 13, first sentence of the final paragraph.* Gough teaches one set of three radially extending electrode tips spaced from a set of only two radially extending electrode tips and Swanson is not relied upon for this claim element.

In applying §103 to this claim, the Examiner attempts to account for the failure to find axially spaced sets of three radially extending electrode tips in Gough and Swanson by the conclusory statements that this claim element is "not critical," that this claim element is "within the skill of one having ordinary skill in the art," that this claim element provides "no unexpected result," and that it is "merely the provision of multiplied parts for multiplied effect." *See Final Office Action, page 22, last line, to page 23, line 2.*

This rejection is disconnected from the legal standards for patentability under 35 USC §103. There is no requirement under §103 to show that individual claim elements are "critical," only that the combination is nonobvious. *See generally, MPEP §2141 Examination Guidelines for Obviousness.*

While unexpected results can be used to show nonobviousness, an assertion of a lack of unexpected results is not a basis for rejection under obviousness. *See generally, MPEP*

§716.02(a) discussing unexpected results. Accordingly, this is not a proper basis for rejecting the claims.

An analysis under §103 considers whether a claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention, not whether the invention is "within the skill" or "grasp" of this individual. This incorrect formulation developed by the Examiner suggests that an ability to practice or understand the invention renders the invention obvious, a position unsupported by current law and incorrect as a basis for a rejection of the claims.

Finally, the broad proposition that multiple parts providing multiple similar functions cannot be patentable if they are nonobvious, is unsupported by the case of *St. Regis Paper Co. v. Bemis Co., Inc. 549 F.2d 833, 193 USPQ 8 (1977)* cited by the Examiner. It is noted that the court in St. Regis relies on the principle that "synergy" is required for invention, an approach that has been repeatedly refuted by the Federal Circuit. *See, Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc., 807 F.2d 955, 1 USPQ2d 1196 (Fed. Cir. 1986)*. The Examiner's repeated reliance on this roundly rejected "multiplicity principle" is legally unfounded and must be overturned.

In the above formal rejections, the Examiner has failed to provide any analysis supporting this rejection that would permit the Applicant the opportunity to rebut the Examiner's reasoning. *See generally MPEP §2143, noting that the court in KSR requires that the analysis supporting a rejection under §103 be made explicit.*

B. Outer surface between the electrode sets is insulated

It is also agreed upon by both the Applicant and the Examiner that neither Gough nor Swanson teach that the outer shaft surface between the electrode sets is insulated. *See Final Office Action, page 14, final paragraph* The Examiner attempts to explain away the failure to

find this claimed element, as before, using standards that are not recognized tests of obviousness under §103. *See Final Office Action, page 23, lines 2-4.*

The Examiner further suggests that a modification of the references to add the missing outer insulation would be motivated by a desire to "make the device more sturdy." This motivation is not disclosed by the prior art of record and the Examiner has provided no basis to suggest that it was a motivation generally recognized in the prior art at the time of the invention. On its face, this purported motivation is fundamentally implausible: a person in the prior art motivated to make a metal shaft sturdier would not add low-strength, relatively easily abraded insulation (typically a thin film of plastic).

The Examiner further suggests that modifying Gough to provide an insulating sleeve between the two sets of antennae would be motivated by a desire to prevent current from being grounded through the shaft (trocar). This purported motivation was not recognized in the cited prior art nor does the Examiner provide any basis for a belief that this motivation was held by those of ordinary skill in the art at the time of the invention. To the contrary, Gough teaches away from this motivation by describing multiple systems none of which provide insulation at this location and further describing embodiments where current flows into the shaft, something that insulation would defeat. *See Gough, column 8, lines 9-12 describing current flow between an antenna 16 and trocar 14.* Gough addresses any potential for short-circuiting by insulating the lower portions of the antennas 16 (as can be seen in Fig. 5 and as is described in multiple examples of Gough), further teaching, contrary to the Examiner's proposed modification, that such insulation is not required to prevent shorting. Thus, none of the reasons offered by the Examiner are a proper basis for rejecting the claims.

IV. Rejection of Claim 8 under 35 USC §103(a)

Claim 8 requires that the first and second axially spaced radially extending electrode sets each have three electrodes that have equal angular spacing about the shaft, and are aligned with each other. There is current flow between the first and second sets. The inventors have determined that this configuration provides for substantially improved volumetric ablation between two planes defined by the respective electrode sets. The Examiner does not contest that the cited references fail to teach this configuration. Gough in Fig. 7 shows unaligned electrodes of different radial extent and is silent with respect to how the electrodes are energized in that embodiment.

The Examiner generally dismisses the claim limitation directed to the number of electrodes under the improper "multiplicity principle" described above and does not consider the limitations of alignment between the two sets of electrodes or their angular separation in the rejection under §103. The Examiner improperly derives motivation to use multiple electrodes from an increased efficacy of the claimed method over that taught by the cited art. Specifically, the Examiner states that the present invention "would ablate the tumor more quickly than the procedure involving rotation", the later being the technique actually taught and enabled by the Gough reference. Using the Examiner's reasoning, an invention is obvious if it presents an improvement over the cited prior art, a paradoxical conclusion clearly divorced from legal standards for obviousness under §103. Accordingly, since all of the limitations of claim 8 are not disclosed in the prior art, and because the Examiner has failed to identify a motivation to modify existing methods within the prior art, the rejection of claim 8 is improper.

V. Rejection of Claim 28 under 35 USC §103(a)

Claim 28 requires that the support shaft be formed of two concentric tubes each with outer insulation. Neither of the cited references teach this shaft configuration. Gough in Fig. 7 shows a single metal tube with an insulating coating only at its proximal end. Swanson in Fig. 2 shows a single tube that is uninsulated along its operative length.

The Examiner does not address this limitation in applying §103 to claim 28 but acknowledges that "two shafts, each composed of a metallic inner portion and on insulated outer portion is not taught by Gough". *See Final Office Action, page 20, lines 3-5.*

VI. Rejection of Claim 29 under 35 USC §103(a)

Claim 29 requires that the support shaft be formed of two tubes positioned in side-by-side configuration to provide a predetermined separation between the radially extending electrode tips. Neither of the cited references teach this configuration.

VII. Responses to Other Arguments

The Examiner makes additional arguments throughout the Final Office Action that do not appear to be directed to particular claims and, in some cases, do not appear to be directed to actual claim limitations.

1. Gough teaches the use of six or more electrodes which would clearly define a plane as required by some claims. *See, Page 11, second paragraph of the Final Office Action.*

The Applicant does not claim electrodes arranged in unspecified planes. Some of the Applicant's claims require two planes defined from three radially extending electrodes. There are numerous ways to arrange six or more electrodes that do not produce the opposed planes defined in the claims, for example, placing all six electrodes at the end of the probe following the teachings of prior art US Patent 5,827,276 cited by Gould as depicted below:

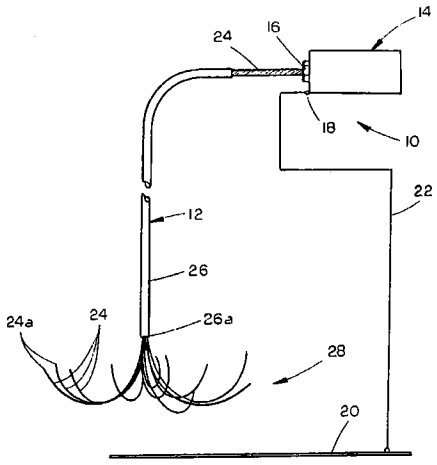


FIG. 1

Any inherency argument, such as the one presented by the Examiner, requires a basis in fact and/or technical reasoning that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).* In this case, two planes defined by radially extending electrodes does not necessarily flow from the use of multiple electrodes of any number, as is demonstrated by the prior art shown above.

> 2. Using bipolar mode to allow current to flow from one electrode to the other along the axis of the device was known. *See, page 11, final paragraph, of the Final Office Action.*

In presenting this argument, the Examiner relies on the cited art of Gough but takes the relevant section of Gough out of context, implying that Gough teaches a *single* probe operated in the bipolar mode between two antennas, which it does not. In fact, Gough states:

> Multiple antenna device[s] 12 can be operated in the bipolar mode between the two antennas 16. *See column 8, lines 5-12.*

A reading of the entire Gould reference makes it clear that the bipolar mode as contemplated and taught by Gough refers to current flow between prongs on two different antenna devices of unknown separation and orientation, distinguishable from flow between sets of electrodes held in axial separation that each define a plane about a tumor volume.

> 3. It would be obvious to provide additional electrodes spaced around the circumference of the shaft since this would provide more uniform treatment. *See, page 13, final paragraph of the Final Office Action*

Whether a particular number of additional electrodes will meaningfully improve the uniformity of heating in human tissue is far outside the expertise of the Examiner. Official Notice of facts that are not capable of "instant and unquestionable demonstration as to defy dispute" require documentary evidence. *See generally MPEP 2144.03 (assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art).* Further, given that additional electrodes incorporate additional costs and complexity, an improvement alone is not sufficient to show that a motivation to make this change was recognized in the prior art

> 4. Gough teaches many variations; accordingly all readily implemented variations are unpatentable.

This argument is implicit in the underlying rejection of the present invention over Gough and incorporates two legally incorrect conclusions. The first is that the test of invention is difficulty of implementation. As noted by the recent Examiner guidelines:

> when a combination invention involves additional complexity as compared with the prior art, the invention may be nonobvious unless an Examiner can articulate a reason for including the added features or steps. This is so even when the claimed invention could have been readily implemented. *See generally, Fed. Reg. Vol. 75 No. 169 pp 53643.*

The second incorrect principle is that an arguable "genus" described by multiple probes disclosed by Gough combined with the Examiner's general statements about nonspecific variations, render all "species" of electrodes with prongs obvious. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).*

> 5. The level of ordinary skill in the art was extremely high as evidenced by the large amount of schooling to which surgeons and physicians are subject. *See, page 15, first paragraph of the Final Office Action.*

The Examiner cannot avoid the burden of proof in establishing obviousness of the invention by simply arguing that the level of skill in the art is high. In this case, it is highly questionable that medical doctors, despite their years of schooling, are experts in the field of electronics or understand how radiofrequency electric currents flow through tissue to the extent that all improvements in these devices would be obvious to them. The lack of objective basis for the Examiner's statement is particularly acute in this case where the state of art must be determined more than six years into the past and the actual state-of-the-art evidenced by the cited references contradicts the Examiner's position. The Applicant has submitted an affidavit by the inventor providing factual basis for the nonobviousness of the present invention at the time of invention to those of ordinary skill in the art that has not been rebutted with any objective factual presentation by the Examiner.

> 6. Gough fails to teach the claimed shaft insulation because Gough wished to "simplify" the description knowing that the omission would be recognized by those of ordinary skill in the art operating the device and receiving "a jolt from the uninsulated proximal portion of the shaft" or when the patient "began to smoke"). *Page 16, last three sentences to page 17, first paragraph of the Final Office Action.*

The Examiner assumes that the probes of Fig. 4 and 5 of Gough, as cited by the Examiner, are inoperative as described and enabled. This unusual conclusion is a result of the Examiner misunderstanding the operation of the Gough reference. The probe of Fig. 4 of Gough, showing no insulation between antennas 16, operates, as explained in Gough, either to provide electrical flow between the antennas 16 of two different probes or from the antennas 16 to the uninsulated shaft 14. In both cases, the uninsulated shaft is at ground potential representing no shock hazard to the user or conduction from the shaft to the patient's skin or tissue. Gough fails to teach insulating the shaft per the present invention because it would interfere with the disclosed operation of the device. The apparently paradoxical position of the Examiner arises only because of the Examiner's misinterpretation of Gough.

The Examiner's argument further illuminates a misreading of the claim limitations of the current invention which do not require insulation of the proximal shaft (that is the portion extending out from the patient) but insulation between the sets of electrodes.

CONCLUSION

The claims of the present invention are properly supported by this specification and illustrated by the figures and the combination of references relied upon does not fairly teach the limitations of claims 1-9, 13, 16-22, and 28-32. Therefore, the Applicant requests that the Board overturn the Examiner's rejection of these claims and pass such claims to allowance.

Respectfully Submitted,

Keith M. Baxter, Reg. No. 31,233
Attorney for Applicant
Boyle Fredrickson, SC
840 North Plankinton Avenue
Milwaukee, WI 53203
Attorney Docket No.: 1512.166

CLAIMS APPENDIX

1. (Previously presented) A method for ablating a volume of tissue in a patient comprising the steps of:

(a) inserting a first support shaft through the patient's skin, the first support shaft having an electrically insulated outer surface;

(b) the first support shaft being inserted with a second support shaft through the patient's skin;

(c) radially extending at least three electrode tips in a first electrode set from the first support shaft at a first position along the first support shaft to three respective radial points defining a first plane surrounding the first support shaft, wherein the first position is spaced a distance from a center of the volume of tissue to be ablated, and wherein the second support shaft has a portion at a second position that is axially displaced by a predetermined distance from the first position, wherein the predetermined axial displacement is determined prior to use by a physician;

(d) radially extending at least three electrode tips in a second electrode set from the axially displaced portion of the second support shaft to three respective radial points defining a second plane surrounding the second support shaft at the second position, wherein the second plane is opposite the first plane by a predetermined separation through the tissue to define a three-dimensional volume of tissue to be ablated; and

(e) in response to bipolar power being applied to the first electrode set and to the second electrode set, causing current flow between the first plane and the second plane and through the three-dimensional volume of tissue; and

(f) wherein a portion of the first support shaft and the second support shaft that extends from the first position to the second position is insulated so as not to drain current from the volume of tissue being ablated.

2. (Previously presented) The method of claim 1, wherein the first and second electrode sets are umbrella electrode sets having at least three radially extensible electrode wires.

3. (Previously presented) The method of claim 2 wherein the three radially extending electrode tips in the first electrode set are aligned with corresponding radially extending electrode tips in the second electrode set.

4. (Previously presented) The method of claim 3, wherein the power is applied in an energy spectrum substantially concentrated in frequencies below 100 kHz.

5. (Previously presented) The method of claim 1, wherein each of the first and second electrode sets includes electrode wires carrying the electrode tips that are selectively extendable from the support shaft.

6. (Previously presented) The method of claim 5, further comprising the step of monitoring a temperature level at each of the electrode wires.

7. (Previously presented) The method of claim 1, wherein the steps of radially extending the electrode tips in the first and second electrode sets comprises radially extending wires of the first and second electrode sets to radial points separated by substantially equal angles.

8. (Previously presented) The method of claim 1, wherein the first and second electrode sets are provided by tripartite electrodes, and the steps of radially extending the first and second sets of electrode tips comprise radially extending the tripartite electrode tips such that each of the tips in the tripartite electrode is offset from another of the tips in the tripartite electrode by substantially one hundred and twenty degrees, and the tips in a first one of the tripartite electrodes are aligned with respective ones of the tips in a second one of the tripartite electrodes.

9. (Previously presented) The method of claim 6, further comprising the step of controlling a voltage applied between the first and second electrode sets of to maintain the temperature within a predetermined temperature range.

10. (Canceled).

11. (Canceled).

12. (Canceled).

13. (Previously presented) The method of claim 3, wherein the power is applied in an energy spectrum substantially concentrated in frequencies below 10 kHz.

14. (Canceled).

15. (Canceled).

16. (Previously presented) An electrode assembly for ablating tumors in a patient comprising:

(a) a shaft configuration comprising a first support shaft and a second support shaft, the first support shaft having an electrically insulated outer surface;

(b) a first electrode set having at least three electrode tips radially extensible from the first support shaft at a first position to three respective radial points defining a first plane surrounding the first support shaft;

(c) a second electrode set having at least three electrode tips radially extensible from the second support shaft to three respective radial points defining a second plane surrounding the second support shaft at a second position that is axially displaced along the first support shaft from the first position by a predetermined distance, said predetermined distance being predetermined in a kit before insertion into the patient by a physician, wherein the second plane is opposite the first plane and is separated from the first plane by a predetermined separation to define a three-dimensional volume of tissue to be ablated between the first plane and the second plane; and

(d) wherein when bipolar power is applied to the first electrode set and to the second electrode set, electrical current flows between the first plane and the second plane and through the three-dimensional volume of tissue; and

wherein a portion of the shaft configuration that extends from the first position to the second position is insulated so as not to drain current from the volume of tissue being ablated.

17. (Previously presented) The electrode assembly of claim 16, wherein each of the first and second electrode sets further comprises at least three electrode wires.

18. (Original) The electrode assembly of claim 16, further comprising at least one temperature sensor coupled to each of the first and second electrode sets.

19. (Previously presented) The electrode assembly of claim 17, further comprising a controller connected to the temperature sensor to receive temperature level signals from each of the first and second electrode sets and to the first and second sets to control the applied power level as a function of the temperature level.

20. (Previously presented) The electrode assembly of claim 19, wherein the electrode wires in each of the first and second electrode sets are electrically isolated, a temperature sensor is coupled to each of the electrode wires, and the controller monitors the temperature at each of the electrode wires and individually controls the power applied to the electrode wires.

21. (Original) The electrode assembly of claim 20, wherein the wires in the first electrode set are axially aligned with the electrode wires in the second electrode set.

22. (Previously presented) The electrode assembly of claim 20, wherein each of the electrode wires in each electrode set are spaced at substantially equal angles around the support shaft.

23-27 (Canceled)

28. (Previously presented) The electrode assembly of claim 16, wherein the first support shaft has a tubular metal inner portion and an insulated outer portion and wherein the second support shaft has a tubular metal inner portion and an insulated outer portion and wherein the first support shaft is disposed within the second support shaft to provide a concentric tube configuration.

29. (Original) The electrode assembly of claim 16, wherein the first support shaft is positioned in a side-by-side configuration with the second support shaft.

30. (Previously presented) An electrode assembly for ablating tumors in a patient, the assembly comprising:

a shaft configuration sized for percutaneous placement, said shaft configuration having at least one outer surface extending to a distal tip;

first and second wire electrode sets extensible radially from the shaft configuration to an extension radius, the first wire electrode set being positionable at a first location adjacent to a tumor volume and offset axially along the support shaft from the second wire electrode set, which second wire electrode set is positionable at a second location offset from the first location about the tumor volume, the first and second electrode set each comprising three wires positionable at angularly offset radial points around the shaft configuration;

a power supply connectable between the first and second electrode sets such that current induced heating in the tumor volume is concentrated; and

wherein the shaft configuration has an electrically insulating outer cover on the outer surface between the first and second locations, said cover extending to the distal tip of the shaft configuration.

31. (Previously presented) The electrode assembly of claim 30, wherein the shaft configuration comprises a first support shaft having a tubular metal inner portion and an insulated outer portion and a second support shaft having a tubular metal inner portion and an insulated outer portion and wherein the first support shaft is disposed within the second support shaft to provide a shaft configuration with concentric tubular portions.

32. (Previously presented) The electrode assembly of claim 30, wherein the shaft configuration comprises a first support shaft that is positioned in a side-by-side configuration with a second support shaft and wherein the shaft configuration is sized for percutaneous placement before being placed in a patient by an axial offset of the first wire electrode set from

the second wire electrode set.

EVIDENCE APPENDIX

Applicant submits the attached declaration of Inventor Dieter Haemmerich under 37 CFR §1.132, currently of record in this application.

RELATED PROCEEDINGS APPENDIX

No decision from a related proceeding has been rendered by a court or this Board.

Corresponding European and Japanese applications have been filed and claims granted.